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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,241	10/22/2003	Huy D. Phan	2024729-7033342001 (03-16)	8377
7590 08/24/2005			EXAMINER	
Bingham McCutchen, LLP Suite1800 Three Embarcadero San Francisco, CA 94111-4067			KASZTEJNA, MATTHEW JOHN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,241

Applicant(s)

PHAN, HUY D.

Examiner

Matthew J. Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 and 39-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on May 16, 2005, amended claims 1, 2, 6, 18, 28, 29 and 34; canceled claim 38; and new claims 40-45 are acknowledged. Claims 1-3, 6-7 and 29 *stand* rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,083,222 to Klein et al. Claims 1-5, 7-39 *stand* rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,483,562 to Schoolman in view of U.S. Patent No. 6,152,923 to Ryan. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,083,222 to Klein et al.

In regards to claims 1 and 29, Klein et al. disclose an ablation device 10 comprising: a shaft 12 comprising proximal and distal ends, a distal portion of the shaft being bendable 22 to form a desired configuration, and a proximal portion of the shaft being rigid; a clamp assembly 26 on the distal end of the shaft, the clamp assembly comprising first 30 and second 32 opposing jaws, at least one of the first and second jaws being movable relative to the other to open and close the clamp assembly; first and

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second electrodes on the first and second jaws, respectively; and a handle 54 on the proximal end of the shaft (see Col. 4, Lines 40-65 and Fig. 1). The apparatus of Klein et al. is considered to be inherently capable of performing the recited method claim.

In regards to claim 2, Klein et al. disclose an ablation device 10 wherein at least a portion of the shaft is capable of being rotated relative to another portion of the shaft about a longitudinal axis of the shaft (see Col. 6, Lines 38-40).

In regards to claim 3, Klein et al. disclose an ablation device 10 where in the shaft comprises a first segment 24 and a second segment 20 rotatably secured to the first segment (see Fig. 1).

In regards to claim 6, Klein et al. disclose an ablation device 10 wherein the distal portion of the shaft is made from a malleable material (see Col. 7, Line 49 – Col. 8, Line 18).

In regards to claim 7, Klein et al. disclose an ablation device 10 wherein the shaft further comprises a lumen 16 extending between the proximal and distal ends (see Col. 4, Lines 40-52).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-5, 7-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,483,562 to Schoolman in view of U.S. Patent No. 6,152,923 to Ryan.

In regards to claims 1, 14, 19, 29, 32-37 and 39, Schoolman discloses a device comprising: a shaft 2 comprising proximal and distal ends, at least a portion of the shaft being bendable 22 to form a desired configuration; a clamp assembly 26 on the distal end of the shaft, the clamp assembly comprising first 12 and second 14 opposing jaws, at least one of the first and second jaws being movable relative to the other to open and close the clamp assembly; and a handle 7 on the proximal end of the shaft (see Col. 3, Lines 20-27 and Fig. 1) but is silent with respect to first and second electrodes on the first and second jaws, respectively. Ryan teaches of an analogous device having a pair of multi-pronged jaw members pivotally attached in opposing relation to one another and selectively movable between open and closed positions. Furthermore the forceps include at least one electrode disposed on the inner facing of each of the jaw members and a switch for selectively controlling electrosurgical energy to each member (see Col. 2, Lines 45-62). It would have been obvious to one skilled in the art at the time the invention was made to dispose first and second electrodes on the clamp assembly in the device of Schoolman in order to provide a tool capable of sealing, cauterizing, coagulating and/or cutting vessels and vascular tissue at multiple sites as taught by Ryan and is well known in the art. The device of Schoolman would then furthermore be inherently capable of performing the recited method claim.

In regards to claim 2 and 25, Schoolman discloses a device wherein at least a portion of the shaft is capable of being rotated about a longitudinal axis of the shaft (see Col. 2, Lines 16-19)).

In regards to claims 3 and 22, Schoolman discloses a device wherein the shaft comprises a first segment 7 and a second segment 2 rotatably secured to the first segment (see Fig. 1).

In regards to claim 4, Schoolman discloses a device wherein the second segment is rotatably secured to the first segment by a ball-bearing connection (Col. 3, Line 63 – Col. 4, Line 7).

In regards to claim 5, Schoolman discloses a device wherein the shaft comprises one or more polymer rings 31. The examiner takes official notice with regards to the use of polymeric substances for the construction of medical devices.

In regards to claims 7 and 20, Schoolman discloses a device wherein the shaft further comprises a lumen extending between the proximal and distal ends (see Fig. 3)

In regards to claims 8 and 21, Schoolman discloses a device further comprising: a tensioning device 150 located proximate to the proximal end of the shaft; and a wire 142 having a proximal end secured to the tensioning device and a distal end secured to the distal end of the shaft, at least a portion of the wire is disposed within the lumen of the shaft; wherein the tensioning device is operable to create or adjust tension in the wire (see Col. 6 ,Lines 20-33).

In regards to claim 9, Schoolman discloses a device wherein the tensioning device comprises a knob 152 (see Fig. 6).

In regards to claim 10, Schoolman discloses a device further comprising: an actuating device 10 coupled to the handle; and a control wire 64 having a proximal end coupled to the actuating device and a distal end secured to the clamp assembly, a t ~~l~~least a portion of the control wire is disposed within the lumen of the shaft; wherein the actuating device is operable to create or adjust tension in the control wire (see Col. 4, Lines 23-48).

In regards to claim 11, Schoolman discloses a device wherein the actuating device comprises a first portion 10 and a second portion 59 rotatably secured to the first portion (see Col. 4, Lines 23-48).

In regards to claims 12 and 23, Schoolman discloses a device further comprising a spring 65 secured between the proximal end of the control wire and the actuating device (see Fig. 1).

In regards to claim 13 and 24, Schoolman discloses a device wherein the clamp assembly is rotatably secured to the distal end of the shaft (see Col. 6, Lines 34-38).

In regards to claim 15, Schoolman discloses a device wherein the second jaw remains approximately parallel to the first jaw as the second jaw is moved relative to the first jaw (see Col. 5, Lines 19-28 and Fig. 4)

In regards to claims 16 and 26, Schoolman discloses a device wherein at least a portion of the first jaw is capable of being bent into a desired shape (see Col. 5, Lines 19-38).

In regards to claims 17-18 and 27-28, Schoolman discloses a device with a clamp assembly but is silent with respect to the first and second electrodes operating in either a bipolar or unipolar arrangement. Ryan teaches of an analogous device having electrodes operating in a bipolar arrangement. Ryan furthermore teaches that is well known in the art that the electrosurgical configuration of such ablating instruments is classified into either a monopolar or bipolar arrangement (see Col. 1, Lines 23-43). It would have been obvious to one skilled in the art at the time the invention was made to include electrodes on the clamp assembly of Schoolman that operate in either the bipolar or monopolar configuration in order to provide options for surgical setup as taught by Ryan and is well known in the art.

In regards to claims 30-31, Schoolman discloses a device inherently capable of performing the recited method claim, further comprising locking the shaft in the desired shape and creating compression in the shaft (see Col. 5, Lines 45-53).

Claims 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,483,562 to Schoolman in view of U.S. Patent No. 6,152,923 to Ryan in further view of U.S. Patent No. 5,902,301 to Olig.

In regards to claims 40-45, Schoolman and Ryan disclose an apparatus inherently capable of ablating a tissue wherein a clamp assembly having a first jaw with a first electrode and a second jaw with a second electrode but are silent with respect to wherein the second jaw is linearly translatable relative to the first jaw. Olig teaches of an analogous apparatus having cutting and coagulating forceps with interleaved electrodes which are capable of being parallel to each other in an open position and

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wherein the second jaw is translatable relative to the first jaw. It would have been obvious to ones skilled in the art at the time the invention was made to construct the jaws in the apparatus of Schoolman and Ryan wherein the second jaw is linearly translatable relative to the first jaw to allow for the clamp assembly to grip tissue more efficiently as taught by Olig.

Response to Arguments

Applicant's arguments filed May 16, 2005 have been fully considered but they are not persuasive.

Applicant states Klein does not disclose or suggest a shaft having a rigid proximal portion. However, Klein discloses an apparatus having an elongated catheter shaft 12 that has a relatively stiff hollow catheter body 14, which is bonded to a relatively flexible deflectable tip 18 (see Col. 4, Lines 40-45). Therefore, as broadly as claimed, Klein discloses an instrument wherein a proximal portion of the shaft is rigid. Furthermore, the applicant states that Klein fails to disclose or suggest the limitation of placing internal tissue between the jaws of a clamp assembly. However, Klein discloses that the pressure of the ablation surfaces of the gripping members onto heart tissue effectively clamps the ablation electrode onto the tissue and thus inherently internal tissue is placed between the jaws of the clamp assembly, as claimed (see Col. 2, Lines 38-53 and Col. 3, Lines 22-25).

Applicant states that Schoolman and Ryan fail to disclose or teach the limitation wherein the second jaw remains approximately parallel to the first jaw as the second jaw is moved relative to the first jaw. However, as seen in Figure 4 of Schoolman, the



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tips 92 and 90 of the clamp assembly remain approximately parallel to one another.

Furthermore, as seen in Figs. 3 and 4 of Ryan the first and second jaws of Ryan are approximately parallel as they hold tissue 51 inside a patient. As broadly as claimed, Ryan and Schoolman disclose the limitations of claims 19 and 34.

In response to applicant's argument that U.S. Patent No. 6,152,923 to Ryan is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Ryan discloses a multi-pronged bipolar forceps which allows a user to selectively apply electrosurgical energy to tissue to effectively seal, cauterize, coagulate and /or cut tissue during open surgical procedures and laparoscopic surgical procedures. Schoolman discloses a flexible shaft device which can be locked in a desired shape having a live tool attachment at a distal end thereof manipulable by a user of the device. Furthermore, Schoolman teaches that an object of his invention is to provide a device capable of having a plurality of suitable devices attachable to the distal end of the shaft for carrying on a plurality of desired work processes. Therefore it would have been obvious to one skilled in the art at the time the invention was made to dispose first and second electrodes on the clamp assembly in the device of Schoolman in order to provide a tool capable of sealing, cauterizing, coagulating and/or cutting vessels and vascular tissue at multiple sites as taught by Ryan and is well known in the art.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK

8/8/05



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